City of Asheville Wellness Program

Introductory Information and Guidelines

Thank you for your interest in the City of Asheville – sponsored Wellness Program(s). The programs are voluntary and designed to help you reach your goals, stay motivated and save you money.

Below is the enrollment paperwork for the Wellness Program(s).

Briefly, here is how the program works:

The City of Asheville will:

- Pay 100% of Diabetes, Asthma and/or Hypertension/Cholesterol classes.
- Eliminate disease-related medicine co-pay and supply costs (please **allow up to 10 working days** from the date your enrollment paperwork is received in Human Resources).
    - Diabetes – 100% waived co-pay on all medications and supplies; pumps with recommendation from Wellness Program and approval from City of Asheville.
    - Asthma – 100% waived co-pay on all medications.
    - Hypertension & Cholesterol – 100% waived co-pay on all medications.
- Pay 100% of required follow-up visits with your assigned care manager (every 1 to 3 months).
- Pay 100% of required lab work / breathing tests (every 6 months to a year).

Your Part:

- Agree to attend education classes related to your diagnosis within 90 days of enrollment (Topics may include Nutrition, Activity, Stress Management, Medications and more).
- Agree to meet with a specially trained Care Manager on a regular basis (every 1 – 3 months).
- Agree to have lab work / breathing test done every 6 months to a year (whichever applicable).

NOTE: You will need to use a local pharmacy for the medications covered by this program. *Do NOT use Express Scripts* mail order for the medications you get through this program. They have not been able to set up the reduced co-payment in their system.

If you choose to become a participant in the Wellness Programs, review, complete, and sign the enrollment packet as well as the corresponding surveys, (click on one of the following): Asthma / Child Asthma / Diabetes / High Blood Pressure/Cholesterol. Then send the **enrollment packet and survey** via interdepartmental mail to the Human Resources Department

MISSION HOSPITALS

EMPLOYER SPONSORED WELLNESS MANAGEMENT PROGRAMS

POLICY AND PROCEDURE FOR PARTICIPATING EMPLOYEES

REQUIREMENTS

- Complete appropriate paperwork. The secretary can guide you with this process.
- Complete regular lab work / spirometry testing requirements (every 3-6 months).
- Complete education sessions at Mission Hospitals' Health Education Center **within 90 days of enrollment.**
- Meet with an assigned Care Manager (pharmacist or educator) on a regular basis.

BENEFITS

- Co-pays will be reduced / waived for all related medications and supplies. If you are unsure if a medication will be covered, address your questions to the coordinator.
- Education sessions at Mission Hospitals' Health Education Center.
- Regular care by an assigned care manager. The Care Manager will assist you in following the care plan your physician has created for you.

MEETINGS WITH THE CARE MANAGER

- Your assigned Care Manager will contact you prior to the scheduled sessions. If a care manager does not contact you, please notify the program Secretary.

CANCELLATIONS AND MISSED APPOINTMENTS

Participants and care managers, alike, are busy people. Therefore, it is crucial that we respect each other's time. The following is required of participants:

- A 24-hour notice must be given to a care manager if you are unable to make a scheduled appointment (unless it is an emergency situation). If you do not provide the notice, the care manager will contact you.
- Upon a second missed appointment without prior notification, the program secretary will contact you about continuing in the program. Remember that this program is voluntary.
- If you choose to not be a part of the program, please contact the program secretary as soon as possible. If you discontinue the program, you may choose to re-enroll after a 6-month period.
- Frequently, when a care manager tries to schedule an appointment with you, he or she may need to leave a message for you. It is very important that you respond to that message in a timely manner (i.e. within one week). Failure to respond will result in a call from the program secretary. If you fail to respond to the program secretary by the date indicated, it will be assumed that you do not want to continue in the program and you will be dropped from the program. You may choose to re-enroll after a 6-month period.

I, _____, understand the following requirements to become a participant in the Disease / Weight Management Program. I agree to follow the above policy and understand that not following the policy may result in my removal from the program.

Participant Signature: _____ Date: _____
(or Guardian)

Mission Hospitals' Informed Consent

Title of Study: Related Aspects of a Wellness Program that Mission Hospitals Sponsors for Employees with Asthma, Diabetes, Hypertension, Hyperlipidemia.

Principal Investigator: Barry A. Bunting, Pharm.D.

Phone number: 828-213-4782

Sponsor: *Mission Hospitals*

You are being asked to take part in a research study. The investigators listed above are in charge of the study; other professional persons may help them or act for them.

What are some general things you should know about research studies?
Research studies are designed to gain scientific knowledge that may help other people in the future. You may not receive any direct benefit from participating. There may also be risks associated with participating in research studies.

Your participation is voluntary. You may refuse to participate, or may withdraw your consent to participate at any time, and for any reason, without risking your future care at Mission Hospitals or your relationship with your doctor. If you are a patient with an illness, you do not have to participate in research in order to receive treatment.

Details about this particular study are discussed below. It is important that you understand this information so that you can decide in a free and informed manner whether you want to participate. You will be given a copy of this consent form. You are urged to ask the investigators named above, or staff members who may assist them, any questions you have about this study at any time.

Mission Hospitals is conducting this study.

What is the purpose of this study?
The purpose of this research study is to determine if an employer sponsored wellness program, that provides self-care education, significantly reduced cost of medications and frequent follow-up with a care manager, will result in measurable improvement in health, and lower overall health care costs for individuals with asthma, diabetes, high blood pressure, and/or high cholesterol.

The focus of the study is improved education and follow-up. The goal is to remove barriers to allow you to successfully manage your disease.

This study does not involve the use of any experimental drugs, procedures, or tests.

How many subjects will participate in this study?
If you decide to participate, you will be one of approximately *1000* subjects in this research study.

How long will your participation last?
Your participation in this study will last as long as you wish. Enrollment is voluntary. If your employer adds this program as a permanent part of their health benefit you may participate as long as you would like or as long as they offer the program.

What will happen if you take part in the study?
During the course of this study, the following will occur:

-You will be asked to participate in education classes related to the disease you have.
-You will also be asked to meet on a regular basis, as often as once a month, for 20-30 minutes with a care manager (pharmacist, nurse, medical social worker or dietitian) who will review your care, help you set health goals, and communicate with your physician regarding your treatment plan. You will be able to have input into choice of a care manager.
-At the beginning of the study you will be asked to fill out forms to provide personal information such as name, address, phone number, age, sex, and social security number.
-You will be asked to answer questions regarding your medical history and every six months you will be asked to fill out some of these questions again.
-You will be asked to either supply laboratory information performed by your doctor or have a blood test done (if applicable) for blood sugar and/or cholesterol if your physician has not done these recently.
-You will be asked to have this testing repeated at least every six months. There is no cost to you for this testing.
-If you are in the asthma program you will be asked to have a breathing test (Spirometry) done at the beginning of the study and repeat every six months.

Are there any reasons you should not participate?
You should not participate in this study if you are unwilling to attend education classes, meet regularly with a care manager, or have the required laboratory (if applicable) or breathing testing (if applicable) done. Participation is voluntary and you may drop out at any time.

What are the possible risks or discomforts?
This study might involve the following risks and/or discomforts to you:

> Routine drawing of blood for standard laboratory testing may result in some discomfort, and a small risk of bruising or infection.

In addition, there may be uncommon or previously unrecognized risks that might occur.

What are the possible benefits?
The benefits to you of participating in this study may be improved self-care skills, improved health, fewer sick-days, reduced complications related to your disease due to better control, and decreased cost of care.

If you choose not to participate, what other options do you have?
You do not have to participate in this research study in order to receive treatment.

What if we learn about new risks during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will your privacy be protected?

Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Mission St. Joseph's Hospital.

As part of the study, Dr. Bunting and his study team will report the results of your study-related laboratory tests, questionnaire answers, and health care costs, anonymously grouped with other people in the study, to interested health care providers (physicians, pharmacists, nurses and dietitians) who deal with these diseases. Changes in the groups overall health and cost of care will be reported to employers who are paying for, or potentially could pay for education, medications, and monitoring services. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration and representatives of Mission Hospitals Institutional Review Board. If your research record is reviewed by any of these groups, they may also need to review your entire medical record. The study results will be retained in your research record indefinitely.

No subjects will be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, Mission Hospitals will take all steps allowable by law to protect the privacy of personal information.

Will you be paid for participating? Will it cost you anything to participate?

You will not be paid for participation in this study, but will receive the benefit of reduced or waived medication co-payments. There are no costs to individuals for participation in this study. Your employer covers the costs.

Who is sponsoring this study?

Mission Hospitals funds the administration of this research study. Your employer is paying for the education, medication, care manager, and laboratory testing. The sponsor is not compensating the research team for the study.

What if you want to stop before your part in the study is complete?

You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concerns an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Mission St. Joseph's Hospital. If you do decide to withdraw, we ask that you contact Dr. Bunting in writing and let him know that you are withdrawing from the study. His mailing address is:

Dr. Barry A. Bunting
Clinical Manager of Pharmacy Department
Mission Hospitals
445 Biltmore Ave. Suite 203
Asheville, NC 28801

The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have further questions, or if a research-related injury occurs, you should call *Barry A. Bunting, Pharm.D.* at *(828) 213-4782*.

What if you have questions about your rights as a subject?
This research has been reviewed and approved by the Institutional Review Board at Mission St. Joseph's Hospital. If you have any questions or concerns regarding your rights as a research subject, you may contact the Chairman of the Committee at (828) 213-1105.

CONSENT TO PARTICIPATE

Your signature below indicates that you have read the above information and you have had an opportunity to ask questions to help you understand what your participation will involve.

By signing this consent form you are not giving up any of the legal rights that you would otherwise have as a participant in a research study.

_____ Please indicate by initialing here that you have received a copy of this consent form.

Your signature also indicates that you voluntary consent to participate in the study.

_____ _____
Signature of Subject Date

_____
Printed Name of Subject

_____ _____
Signature of Person Conducting Consent Discussion Date

_____
Printed Name of Person Conducting Consent Discussion

AUTHORIZATION OF USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES

The privacy law, Health Insurance Portability & accountability Act (HIPAA), protects your individually identifiable health information (protected health information). The privacy law requires you to sign an authorization (or agreement) in order for researchers to be able to use or disclose your protected health information for research purposes in the study entitled Related Aspects of a Wellness Program that Mission Hospitals Sponsors for Employees with Asthma, Diabetes, Hypertension, Hyperlipidemia. Please read the information below to see if you agree to allow the use of your protected health information for this study.

Who will have access to your protected health information related to your participation in this research study?

- Only the principal investigator, Barry Bunting, Phram.D, Sharon West, RN, and Martha Suarez, Secretary, and your Care Manager will have access to study information that is identifiable as yours.

What protected health information will be used or disclosed?

- Health information that will be used for this study, but reported anonymously, includes: age, sex, weight, laboratory results, Hemoglobin A1c (where applicable), cholesterol (where applicable), spirometry (where applicable), blood pressure (where applicable) and the responses to disease specific questionnaires that provide medical history, symptoms, list of medications, and health related behaviors (nutrition, activity, smoking history). In addition data on the cost of health care for the study group will be tracked and reported.

What will your protected health information be used for?

- This information will be used to determine if an employer sponsored wellness program that provides improved access to medication, education, and frequent follow-up with a care manager will result in clinical improvement and lower overall health care costs.

Who will the researchers share your protected health information with?

- The Mission Hospitals Institutional Review Board.
- Government representatives, such as the Food and Drug Administration and the Office of Human Research Protections when required by law.
- This information may be shared with your physician or health educator (e.g. diabetes educator who is instructing classes you are participating in).
- Individual, but unidentifiable, information will be shared with statisticians for statistical analysis of the study group.
- When laboratory testing is done it will be necessary for laboratory personnel to know who the individuals are that are being tested.
- Information on the group outcomes, but not individual outcomes may be reported in medical and/or pharmaceutical journals.

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization. The researchers agree to protect your health information by using and disclosing it only as permitted by you in this Authorization and as directed by state and federal law.

You do not have to sign this Authorization. If you decide not to sign the Authorization:

- It will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.
- You may not be allowed to participate in the research study.

After signing the Authorization, you can change your mind and:

- Not let the researcher disclose or use your protected health information (revoke the Authorization).
- If you revoke the Authorization, you must send a written letter to Barry Bunting to inform him of your decision.
- If you revoke this Authorization, researchers may only use and disclose the protected health information **already** collected for this research study.
- If you revoke this Authorization your protected health information may still be used and disclosed should you have an adverse event (a bad effect).
- If you change your mind and withdraw the Authorization, you may not be allowed to continue to participate in this study.

You may not be allowed to review the information collated for the research until after the study is completed. When the study is over, you will have the right to access the information again.

This Authorization does not have an expiration date.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions or concerns about your privacy rights in this research study, you should contact the Chairperson of the Mission Hospitals' Institutional Review Board at (828) 213-1105.

I authorize Barry Bunting and his research staff to use and disclose my protected health information for the purposes described above. I also permit my doctors and other health care providers to disclose my protected health information for the purposes described above.

I am the subject or am authorized to act on behalf of the subject. I have read this information, and I will receive a copy of this form after it is signed.

_____	_____
Signature of research subject or *Research subject's legal representative	Date
_____	_____
Printed name of research subject or *Research subject's legal representative	Representative's relationship to research subject

*Please explain Representative's Relationship to Patient and include a description of Representative's Authority to act on behalf of Patient:

_____

_____

***__PATIENT INFORMATION__ **(Please complete ALL appropriate questions)**

SSN_____ DOB_____ GENDER (Please circle one) M F

LAST NAME_____ FIRST NAME_____ MIDDLE NAME_____

MAIDEN NAME_____ RACE_____ NATION/COUNTRY_____

ADDRESS_____ HOME PHONE_____

CITY/STATE/ZIP_____WORK PHONE_____

EMAIL ADDRESS _____ CELL PHONE _____

DAYTIME PHONE NUMBER: _____ MARITAL STATUS (Please circle one) M S W D Separated

EMPLOYER_____ STATUS (Please circle one) Full-time Part-time
(Please state if RETIRED, DISABLED, SELF EMPLOYED or UNEMPLOYED)

PRIMARY PHYSICIAN _____ SPECIALIST _____

***__GUARANTOR__ **(To be completed by parent/legal guardian if PATIENT is a MINOR)**

LAST NAME_____ FIRST NAME_____ MIDDLE NAME_____

MAIDEN NAME_____ RACE_____ NATION_____

ADDRESS_____ HOME PHONE_____

CITY/STATE/ZIP_____WORK PHONE_____

MARITAL STATUS (Please circle one) M S W D Separated

EMPLOYER_____ STATUS (Please circle one) Full-time Part-time
(Please state if RETIRED, DISABLED, SELF EMPLOYED or UNEMPLOYED)

***__EMERGENCY CONTACT INFORMATION__

NAME_____ RELATIONSHIP_____

WORK PHONE_____ HOME PHONE_____

***__INSURANCE INFORMATION__ **(State if MCAID, MCARE, OR SELF PAY)**
(Complete if primary and policyholder is different from patient OR insurance is secondary)

POLICY HOLDER'S NAME_____ SSN_____

DOB_____ RELATIONSHIP_____ EMPLOYER_____

****To be completed by clinician**
INSURANCE CARD COPIES ATTACHED (Please circle one) YES NO (Front and back of cards needed)

MSQP ATTACHED (Please circle one) YES NO N/A *MUST HAVE IN ORDER TO COMPLETE REGISTRATION

Appointment Log - Health Education Center

(FOR OFFICE USE – THIS PAGE ONLY)

DATE: _____ Staff Completing Info. _____

PATIENT NAME _____DOB_____ DAYTIME PHONE_____

APPOINTMENT INFORMATION

Circle Appropriate choice: Schedule Reschedule

Appointment type:

HE Asthma Education Initial | HE Asthma Education F/U | HE Diabetes Initial Assessment | HE Dbs Self Care Course
HE HTN/Lipids Enrollment | HE HTN/Chol Assessment | HE HTN/Chol Self Care Course | HE Lifestyles for Health Course
HE Dbs Meal Planning Initial Visit | HE Nutrition Eval. / Consult. | HE Pharmacist/Care Mgr. Assess.
HE Pharmacist/ Care Manager F/U | Other:_____

Physician:_____

ICD-9 Code:

493.90	Asthma	271.3	Glucose Intolerance	648.83	Diabetes w/pregnancy
250.01	Type 1 Diabetes	250.03	Type 1 Diabetes, uncontrolled	277.7	Metabolic Syndrome
250.00	Type 2 Diabetes	250.02	Type 2 Diabetes, uncontrolled	790.29	Pre-Diabetes (Abnormal glucose tol. test)
272.4	Hyperlipidemia	401.9	Hypertension	278.00	Obesity
Other	_____	571.8	Fatty Liver	770.82	Obstructive Sleep Apnea

Employer Sponsored Wellness Program Participant? YES NO Asthma Diabetes HTN/Cholesterol

□ Mission — If yes, enter diagnosis field: "Condition Code A1 and verify Insurance @ 100%
McDowell
Spruce Pine — If yes, enter diagnosis field: "Condition Code A1 and verify Insurance @ 100%
□ City of Asheville
□ Southeastern Container — If yes, enter diagnosis field: "Condition Code A1 and verify Insurance @ 100%
Other _____

Notes Regarding Attempts to Make Appointment

		Initials of Caller

Appointment Date: _____ Time: _____

DETAILED INFORMATION

1. Which of the following best describes your race/ethnicity? (Check one)
   - ☐ White / Caucasian
   - ☐ Black / African American
   - ☐ Hispanic / Spanish
   - ☐ American Indian / Alaskan Native
   - ☐ Asian / Oriental or Pacific Islander
   - ☐ Other _____

2. What is your primary spoken language? (Check one)
   - ☐ English
   - ☐ Spanish
   - ☐ Other: _____

3. What is the last grade or year of school that you finished? (Check one)
   - ☐ Less than seventh grade
   - ☐ 7^{th} – 11^{th} grade
   - ☐ High school graduate or obtained GED
   - ☐ Some college or vocational training
   - ☐ College graduate
   - ☐ Post-Graduate

4. Do you have any financial concerns? (Check one. If yes, please explain)
   ___No ___Yes: _____

RISK ASSESSMENT AND MEDICAL HISTORY

1. Do you have high blood pressure? __ NO __ YES If yes, when diagnosed?_____
2. Do you have High Cholesterol or Triglycerides? __ NO __ YES If yes, when diagnosed?_____
3. Do you have Diabetes? __ NO __ YES __ Type 1 or __ Type 2 When diagnosed?_____
4. Do you have Asthma? __ NO __ YES If yes, when diagnosed?_____
5. Are you overweight or obese? __ NO __ YES

IF YES to any of the above, how are you currently managing your diagnosis?

__ Diet __ Exercise __ Weight Reduction __ Prescribed Medications __ None __ Other: _____

HEALTH CARE INFORMATION

Name of Primary Doctor: _____

Address: _____ Phone: _____

City/State/Zip: _____ Specialty: _____

When did you last see this doctor? _____

Name of Specialist: _____

Address: _____ Phone: _____

City/State/Zip: _____ Specialty: _____

Please answer YES or NO to the following questions:

Do you smoke cigarettes?……..	Yes	No
If you are female, are you postmenopausal?…….	Yes	No
If you are female, are you on hormone replacement therapy?……..	Yes	No
Do you have a mother or sister who had a heart attack or bypass heart surgery before the age of 65?	Yes	No
Do you have a father or brother who had a heart attack or bypass heart surgery before the age of 55?	Yes	No
Has your doctor ever told you that your heart is enlarged?……	Yes	No
Have you ever had a heart attack?……..	Yes	No
Have you ever had angina, chest pains that your doctor told you were likely related to your heart?…	Yes	No
Have you ever had heart surgery to open up blood vessels in your heart?…….	Yes	No
Do you have heart failure, a condition in which your pump is weakened?……	Yes	No
Have you ever had a stroke or "mild strokes" also known as transient ischemic attacks (TIA)?……..	Yes	No
Do you have kidney disease that you have been told is related to high blood pressure or diabetes?…	Yes	No
Do you have peripheral arterial disease or "hardening of the arteries?"……	Yes	No
Have you ever been told you have eye disease that is related to high blood pressure or diabetes?…..	Yes	No

Please indicate whether you have, or have had any of the following conditions:

Depression……	Yes	No	Kidney Disease……	Yes	No
Arrhythmia (irregular heart beat)	Yes	No	Osteoporosis (thinning bones)	Yes	No
Benign Prostatic Hypertrophy (BPH – enlarged prostate)	Yes	No	Sexual Dysfunction…….. (Problems with sexual performance)	Yes	No
Gout……..	Yes	No	Thyroid Disease……	Yes	No
Lung Disease (COPD)…….	Yes	No	Liver Disease……	Yes	No

Other medical conditions that you have or have had?_____

List any allergies:_____

Do you drink alcohol? Yes No Please indicate quantity and frequency:_____

Do you have a history of using illegal substances?_____

Pharmacy preference / location: _____

Are you currently taking any medications (prescribed, over-the-counter, herbal/homeopathic, home remedies)? Yes No

***Please list all medications that you are currently taking:

NAME OF MEDICATION	STRENGTH	HOW MUCH / HOW OFTEN

(If additional space is needed, please continue on back or attach separate sheet of paper.)

Surveys:

Adult Asthma Child Asthma Diabetes High Blood Pressure/Cholesterol